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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,859	09/22/2003	Konrad Basler	Q-77377	4459

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EXAMINER
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CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/664,859

Applicant(s)

BASLER ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 61-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61, 63-66 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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This Office Action is in response to the paper filed on May 23, 2006. Claims 1-60 have been cancelled. Claims 61-66 are currently pending and are under examination.

Priority is set to July 28, 2000.

**Withdrawal of Objections and Rejections:**

The objection to the application for containing sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), is withdrawn.

The objection to the disclosure because of informalities is withdrawn.

The objection to the disclosure because it contained an embedded hyperlink and/or other form of browser-executable code is withdrawn.

The rejection of Claims 61-66 under 35 U.S.C. 112, second paragraph, is withdrawn

**Maintenance and additions to Maintained Rejections:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61 and 63-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding the written description for dlgs fragments SEQ ID NO: 2, 4, 6, 8, or 10, SEQ ID NO: 2 has been shown to bind Doll (page 37). However, the specification fails to address any

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activity associated with SEQ ID NO: 4, 6, 8, or 10. Thus, without a correlation of structure to function, these sequences lack written description.

This part of the written description rejection as set forth in the previous Office Action has not been addressed.

New to this rejection based on amendments to the claims:

Claim 61 and (iv) and (v) disclose SEQ ID NO: 24 and 25, respectively. However, there is no basis in the specification for these sequences, wherein Xaa is any amino acid sequence. Perusal of Figure 7B and the commentary in the specification at page 5 as indicated by Applicants in their response, does not teach that any amino acid can be substituted where the amino acids are not exactly matched between LGS and BCL9 in domains 1 and 2. Therefore, these sequences are new matter.

Additionally, while Claim 61(iii) refers to fragments able to inhibit tcf-driven luciferase activity in colon cells, the specification does not teach or suggest that fragments SEQ ID NO: 2, 4, 6, 8, or 10 would have this activity. Therefore, the new limitations of dependent Claim 63 is new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 61(ii-v), 63, and 66 are again rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (Pub. No. US 2005/0208558). Venter et al.'s SEQ ID NO: 3129 is the same as SEQ ID NO: 3135 in Venter et al's provisional application 60/191,637, filed March 23, 2000.

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Ventner et al.'s SEQ ID NO: 3135 shares 97.2% sequence identity with instant SEQ ID NO: 23 (1423/1464; Claim 61(iii)) as set forth in the previous Office Action.

Regarding fragments, SEQ ID N: 2, 4, 6, 8, and 10 can be found at amino acid positions 323-334, 520-554, 711-725, 760-768, and 773-884, respectively, in Venter et al.'s SEQ ID NO: 3129 as set forth in the previous Office Action (Claim 63). Therefore, Ventner et al.'s SEQ ID NO: 3135 is a polypeptide *comprising* a fragment of instant SEQ ID NO: 23 (Claim 61(iii)), wherein the fragment is SEQ ID N: 2, 4, 6, 8, or 10 (Claim 63).

Newly added SEQ ID NO: 24 (Claim 61(iv)) and SEQ ID NO: 25 (Claim 61(v)) are found at amino acid residues 323-350 and 520-554 of Ventner et al.'s SEQ ID NO: 3135. Therefore, Ventner et al. teach a polypeptide *comprising* a peptide having SEQ ID NO: 24 and/or SEQ ID NO: 25.

At para.[0016] of Venter et al., these polypeptides are placed in pharmaceutical compositions, as set forth in the previous Office Action (Claim 66).

**New Rejection:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61(iv, v) and 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

SEQ ID NO: 24 and 25 have 43% and 67% of their amino acids varied, respectively. Thus, the sequences do not share at least 90% identity within themselves. Thus, it is not clear what the limitations of a polypeptide comprising a peptide having at least 90% identity to SEQ ID NO: 24 are because only 57% of the amino acids in SEQ ID NO: 24 are fixed, for example.

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Claim 61(i) and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Karen Cochrane Carlson PhD". The signature is fluid and cursive, with the "P.D." at the end being more distinct.

**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**